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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,551	08/07/2006	Stig Olmar	P08984US01/BAS	8295
881 7590 12/10/2009 STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			EXAMINER D'ANGELO, MICHAEL J	
			ART UNIT 3735	PAPER NUMBER
			MAIL DATE 12/10/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/588,551

Applicant(s)

OLLMAR ET AL.

Examiner

MICHAEL D'ANGELO

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 79-82 and 86-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 79-82 and 86-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Receipt is acknowledged of applicant's amendment filed on August 31st, 2009. Claims 79-82 and 92 have been amended. Claims 83-85 have been cancelled. Claims 94-95 have been added. Claims 79-82 and 86-95 are pending and an action on the merits is as follows.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
2. A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
3. Claims 79-82, 88-89, and 91-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jersey-Willuhn (US 2003/0216663) in view of Steil et al. (US 2003/0130616).

Regarding claim 79, Jersey-Willuhn discloses at least one pair of electrodes consisting of an injection electrode for injection of an electrical current into a body and sensing electrode for detecting the current after it flows through the body (paragraph 92), where the electrodes are adapted for electrically conductive contact with the body tissue (paragraphs 92-94, see figure 3), a means for measuring the impedance of said current (paragraph 94), and measuring glucose concentrations (paragraph 154, but fails to specifically disclose a processor for correlating the measured impedance with a

predetermined relationship between impedance and glucose levels and determining the glucose level based upon the impedance measurement.

However, Steil discloses a microprocessor operatively connected to the means for measuring impedance for determining the amount of glucose in the body fluid based upon the impedance measurements using a predetermined relationship (controller-12, view figure 1, paragraph 319, line 8 and paragraph 320, lines 8-11).

4. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the physiological monitor of Jersey-Willuhn to include a processor for correlating the measured impedance with a predetermined relationship between impedance and glucose levels and determining the glucose level based upon the impedance measurement as taught by Steil as it is well known in the art to take a tissue impedance and measure a glucose concentration from it.

5. **Regarding claims 80-82**, Jersey-Willuhn discloses the system comprising one pair and two pairs of said electrodes (paragraphs 92-94, see figure 3), and where the body tissue is skin (paragraph 56).

6. **Regarding claims 88-89 and 91-93**, Jersey-Willuhn fails to disclose that the microprocessor is operatively connected to an insulin pump and includes means to adjust the amount of insulin flow via the pump to the subject based on the determined glucose level, a means for calibrating the apparatus against a directly measured glucose, an indicator comprising a visual display connected to the processor for indicating the determined amount of glucose, and the apparatus is implanted in the body tissue for which the impedance is to be measured.

However, Steil discloses that the microprocessor is operatively connected to an insulin pump and includes means to adjust the amount of insulin flow via the pump to the subject based on the determined glucose level (abstract, view figure 1, paragraph 98, lines 30-35), a means for calibrating the apparatus against a directly measured glucose level (paragraph 248, lines 1-8, view figure 32), an indicator comprising a visual display connected to the processor for indicating the determined amount of glucose (paragraph 240), and the apparatus is implanted in the body tissue for which the impedance is to be measured (paragraph 318, lines 1-4).

7. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the physiological monitor of Jersey-Willuhn to include that the microprocessor is operatively connected to an insulin pump and includes means to adjust the amount of insulin flow via the pump to the subject based on the determined glucose level, a means for calibrating the apparatus against a directly measured glucose, an indicator comprising a visual display connected to the processor for indicating the determined amount of glucose, and the apparatus is implanted in the body tissue for which the impedance is to be measured in order to provide a system that can easily notify the user of their glucose levels as well as provide a means for keeping the users glucose in a health range therefor increasing safety.

8. Claims 86 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willuhn (US 2003/0216663) in view of Steil et al. (US 2003/0130616) and further in view of Purvis et al. (US 2004/ 0182719).

9. **Regarding claims 86 and 87**, Jersey-Willuhn as modified by Steil discloses a source of electrical current connected to the injection electrodes (view figure 4 of Bryenton, Bio-impedance source), and where the electrical current is provided at an array of frequencies between 1Hz and 10 MHz (paragraph 72 of Bryenton), but fails to disclose an amperometer or a voltmeter, wherein the amperometer and current source are connected to the injection electrodes and the voltmeter is connected to the sensing electrodes.
10. However, Purvis discloses an amperometer and a voltmeter (paragraph 5, lines 9-11 and paragraph 12, lines 1-4), wherein the amperometer and current source are connected to the injection electrodes and the voltmeter is connected to the sensing electrodes (paragraph 5, lines 9-11 and paragraph 12, lines 1-4).
11. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify a physiological monitor similar to that of Jersey-Willuhn, as modified by Steil to include an amperometer and a voltmeter, wherein the amperometer and current source are connected to the injection electrodes and the voltmeter is connected to the sensing electrodes, as taught by Purvis, in order to control the voltage and sense the voltage/current.
12. Claim 90 is rejected under 35 U.S.C. 103(a) as being unpatentable over Willuhn (US 2003/0216663) in view of Steil et al. (US 2003/0130616) and further in view of Abreu (US 2002/0049389).

13. **Regarding claim 90**, Jersey-Willuhn as modified by Steil fails to disclose that the processor is programmed to determine the glucose level based on a principal component analysis and a partial least square regression analysis.

However, Abreu discloses a processor programmed to determine the glucose level based on a principal component analysis and a partial least square regression analysis (paragraph 296, lines 6-8, the examiner notes that although the disclosure of Abreu is not directed toward using skin impedance the use of principal component analysis and a partial least square regression taught by abreu can be applied to any physiological signal to reduce processing variability).

14. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify a physiological monitor similar to that of Jersey-Willuhn, as modified by Steil to determine the glucose level based on a principal component analysis and a partial least square regression analysis as taught by Abreu in order to reduce variability due to tissue structure.

15. Claim 94 is rejected under 35 U.S.C. 103(a) as being unpatentable over Willuhn (US 2003/0216663) in view of Steil et al. (US 2003/0130616) and further in view of Caduff (US 7,315,767).

Regarding claim 94, Jersey-Willuhn as modified by Steil fails to disclose that the electrodes are in a concentric arrangement where the injection electrodes surround the sensing electrodes.

However, Caduff discloses an impedance measuring device for determining glucose concentration where the electrodes are in a concentric arrangement where the

injection electrodes surround the sensing electrodes (see figure 2, electrodes 18 and 19).

16. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify a physiological monitor similar to that of Jersey-Willuhn, as modified by Steil to incorporate that the electrodes are in a concentric arrangement where the injection electrodes surround the sensing electrodes as taught by Caduff in order to provide an arrangement that is smaller in size therefor would impede the user less and provide a less physically restrictive system.

17. Claim 95 is rejected under 35 U.S.C. 103(a) as being unpatentable over Willuhn (US 2003/0216663) in view of Steil et al. (US 2003/0130616) and further in view of Ollmar et al. (US 2003/0220581).

Regarding claim 95, Jersey-Willuhn as modified by Steil fails to disclose an impedance depth between .1-2mm.

However, Ollmar discloses measuring impedance using the Scibase II (paragraph 112, the examiner notes that in the applicant's specification on page 11 lines 2-4 it is cited that the Scibase II is used to measure impedance at a depth range of 0.1-2 mm. Ollmar discloses using the Scibase II therefore it can be said to meet the limitation of the required depth).

18. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify a physiological monitor similar to that of Bryenton, as modified by Steil to incorporate an impedance depth between .1-2mm as taught by Ollmar in order

to provide a device that can vary the penetration depth, providing a more accurate system.

Response to Arguments

Applicant's arguments with respect to claim 79 have been considered but are moot in view of the new ground(s) of rejection. The argument that Steil fails to disclose the use of only two electrodes for the impedance determination is moot in light of the use of Jersey-Willuhn which discloses using pairs of electrodes consisting of injection and sensing electrodes for determining biological impedance for further blood glucose determinations. Steil is only being incorporated to teach the use of a processor for creating a relationship between the Impedance and the blood glucose.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL D'ANGELO whose telephone number is (571) 270-7112. The examiner can normally be reached on Monday-friday 9-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner, Art Unit 3735

/MD/
Examiner, Art Unit 3735

